SEP 2 1 2001

K012456

510(k) SUMMARY
FOR
SODEM HIGH SPEED SYSTEM (ELECTRIC)
(EAR, NOSE AND THROAT)

1. COMPANY NAME AND ADDRESS

Applicant:	**Sodem**systems Sodem Diffusion SA 110, Ch. du Pont-du-Centenaire CH-1228 Geneva, Switzerland
Contact Person:	Carole BURNIER
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Manufacturing site:	**Sodem**systems Sodem Diffusion SA 110, Ch. du Pont-du-Centenaire CH-1228 Geneva, Switzerland
Date:	20/07/01

2. DEVICE NAME

Classification Name:	- Drills surgical ENT (electric and pneumatic) including Hand piece
Proprietary Name:	Sodem High Speed System (Electric)
Common Name:	Powered Surgical Drill

3. PREDICATE DEVICES

The Sodem High Speed System (Electric) claims equivalence to the following systems:

- Stryker: Total Performance System (TPS) **(K943569)**
- Linvatec: E9000/Advantage **(K990524 / K002523)**

4. DEVICE DESCRIPTION

The Sodem High Speed System (Electric) is a complete system including:
- two motors (*a Skull Perforator motor** and a High Speed motor),
- a foot pedal,
- a console allowing to connect the motors and to select their max. operating speed,
- dedicated wires to connect the motors, the foot pedal and the console,
- attachments/spindles,
- drills, burs and cutters

** A separate 510(k) Premarket Notification has been submitted for neuro/spine surgery, so on this 510(k) submission, we will cover only the High Speed Motor and its use in ear, nose and throat surgery.*

The motor is to be attached to the Sodem High Speed console and is operated with a foot pedal.

The Sodem High Speed System (Electric) is an electrical system developed in conformity with the norms IEC 60601 and UL 2601.

The Sodem High Speed System (Electric) is very similar in terms of use and technological characteristics to products currently on the market (TPS from Stryker and E9000 / Advantage from Linvatec).

Also, the Sodem High Speed System (Electric) is equivalent in terms of use with the Sodem High Speed System (Pneumatic) already submitted (K954717).

5. INTENDED USE

The Sodem High Speed motor allows the fixation of spindles, which operate with drills, burs and cutters for drilling, cutting and sculpting hard tissue and bone for ear, nose and throat surgery.

Motor, attachments and cutting tools are for use in ear, nose and throat surgery.

6. BASIS FOR CLAIM OF SUBSTANTIAL EQUIVALENCE

The Sodem High Speed System (Electric) claims substantial equivalence to other currently marketed high-speed electric power systems. This claim is based on equivalence in:

Intended use
The Sodem High Speed System (Electric) and predicate electric instruments share the same clinical applications and intended used (ear, nose and throat surgery).

Materials
Patient contact materials for all systems consist of surgical stainless steel.

Sterility Status
All systems are supplied non-sterile except drills and burs (special 510k N°K994175 for sterile drills and burs), requiring reprocessing between surgical applications. Sterilization of all systems is accomplished using steam. All systems require decontamination after use, and resterilization by the user facility.

System Description

- **Console**

  All cited systems are operated using an electrical power console. Console allows to select motors and to choose operating speed. All console provide one or more connection for several hand pieces/motors (ex E9000 of Linvatec one connection for 14 hand pieces, TPS of Stryker 3 connections for approximately 10 hand pieces). Difference between Sodem console and other currently marketed consoles is that Sodem console has two specific connection (one for High Speed Motor, and one for *Skull Perforator Motor*, an inversion is not possible).

- **Accessories**

  The Sodem High Speed System (Electric) and predicate systems consist of various attachments (burs, spindles). All offer a wide variety of accessories including but not limited to chuck, adapters, spindles and burs. The technical characteristics of the various adapters are identical or similar. That is, adapters allow the use of hand pieces with various power system accessories.

  Some hand pieces are designed with a terminal angle (nose piece). The Sodem and Stryker systems have an angled nose. The Linvatec E9000 / Advantage systems have an integral angling capability from straight to 20 degrees with a twist of the collet. All systems feature to ability to change burs and spindles without the need for a wrench.

- **Electrical power**

All cited systems are operated using an electrical power source controlled by a foot pedal. For all systems, users can choose maximum operating speed on the console and with the foot pedal increase or reduce speed until maximum speed selected.

The nominal power output of the Sodem High Speed System is identical or substantially equivalent to the other commercially available electrical motors (Linvatec, Stryker). The maximum drill speed of the Sodem High Speed System (Electric) is adjustable with the console from 0-80'000 rpm, the drill speed of the E9000 / Advantage system of Linvatec is adjustable with the console from 0-80'000 rpm, the drill speed of the TPS of Stryker is adjustable with the console from 0-75'000 rpm.

Based on the above comparison, SodemSystems believes that the Sodem High Speed System (Electric) is substantially equivalent to the systems cited, that any differences between the Sodem High Speed System (Electric) and these other currently available powered systems are minor and raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

Sodemsystems
c/o Carole Burnier
Quality & Regulatory Affairs Manager
Sodem diffusion SA
110,ch. Du Pont-du-Centenaire
CH –1228 Geneva
Switzerland

Re: 510(K) Number: K012456
Trade/Device Name: Sodem High Speed System (Electric)
Regulation Number: 21 CFR 874.4250
Regulatory Class: Class II
Product Code: ERL
Dated: July 27, 2001
Received: August 01, 2001

Dear Ms. Burnier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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7.1 Intended Use

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(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012456

Prescription Use ✓
(Per 21 CFR 801.109)